



## Telix Launches New Prostate Cancer Imaging Agent, Gozellix, in U.S.

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MELBOURNE, Australia and INDIANAPOLIS, June 11, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix", "the Company") today announces that its next-generation PSMA-PET imaging <sup>1</sup> agent for prostate cancer, Gozellix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection), is now commercially available nationally in the United States (U.S.).

Gozellix is available through Telix's comprehensive network of distribution partners, Cardinal Health, Inc., PharmaLogic Holdings Corp., Jubilant Radiopharma, and RLS Radiopharmacies.

After radiolabelling with <sup>68</sup>Ga, Gozellix is indicated for PET<sup>2</sup> scanning of PSMA<sup>3</sup> positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, and those with suspected biochemical recurrence (BCR) based on elevated serum prostate-specific antigen (PSA) level. Gozellix builds on proven diagnostic excellence to provide early and accurate detection of metastases at initial staging, with 90% specificity<sup>4</sup>. This clinical performance enables detection of millimetre-scale micrometastases, at PSA levels as low as 0.02 ng/mL<sup>5</sup>. These valuable insights enable physicians to make more informed clinical decisions.

In recent years, PSMA-PET imaging has become established as the standard of care for staging and identifying biochemical recurrence of prostate cancer<sup>6</sup>. However, only a relatively small fraction of the 3.4 million men living with prostate cancer in the U.S. have benefited from this technology, in part due to access and availability challenges<sup>7,8</sup>. Telix has applied for reimbursement for Gozellix, for Medicare-eligible patients in the hospital outpatient setting<sup>9,10</sup>.

Gozellix's enhanced formulation, with an extended "hot" shelf-life of up to six hours, offers a greater level of patient access and convenience through an extended transportation distance and clinical administration window. Telix estimates that up to 20% of PET cameras in the U.S. are beyond the reach of currently available PSMA-PET imaging agents due to distribution efficiency constraints<sup>11</sup>. By overcoming this limitation, Gozellix can improve access for prostate cancer patients, regardless of where they live, with greater scheduling flexibility for clinicians and their patients.

Gozellix can be either centrally produced with a cyclotron or locally prepared with a gallium generator with up to 500mCi of activity, enabling greater production flexibility and on-demand capacity. Cyclotron-based production of Gozellix is supported by the ARTMS QUANTM Irradiation System® (QIS®), the market-leading cyclotron solid target irradiation system<sup>12</sup>.

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, "We are pleased that Gozellix, our next-generation prostate cancer imaging product, is now available coast-to-coast across the United States. Telix is committed to innovation in PSMA imaging, and Gozellix is a result of this focus. It delivers a new level of flexibility in distribution, production and scheduling, along with the high standard of service and reliability that customers have come to expect from Telix."

### About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Brazil, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved by the U.S. FDA<sup>13</sup>, by the Australian Therapeutic Goods Administration (TGA)<sup>14</sup>, by Health Canada<sup>15</sup>, by the Brazilian Health Regulatory Agency (ANVISA)<sup>16</sup>, by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)<sup>17</sup>, by the French National Agency for the Safety of Medicine and Health Products (ANSM), by the German Federal Institute for Drugs and Medical Devices (BfArM), and in multiple other countries within the European Economic Area (EEA) following a positive decentralized procedure (DCP) opinion by the German medical regulator. Gozellix (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) has been approved by the U.S. FDA<sup>18</sup>.

**ARTMS** is a Telix company, and its core technology platform is the [QUANTM Irradiation System® \(QIS®\)](#): a complete cyclotron-based isotope production system designed to support high efficiency, large-scale and cost-effective production of commercially important medical isotopes.

Visit [www.telixpharma.com](http://www.telixpharma.com) for further information about Telix, including details of the latest share price, ASX and SEC filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

### Telix Investor Relations

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### IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS

#### Risk for Misinterpretation

Image interpretation errors can occur with Gozellix PET. A negative image does not rule out the presence of prostate cancer, and a positive image does not confirm the presence of prostate cancer. Gallium Ga-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include

histopathological evaluation of the suspected prostate cancer site, is recommended.

#### Imaging Prior to Initial Definitive or Suspected Recurrence Therapy

The performance of Gozellix for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of Gozellix for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

#### Radiation Risks

Gallium Ga-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

#### Hypersensitivity Reactions

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

#### **ADVERSE REACTIONS**

The safety of gallium Ga-68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMABCR studies, each receiving one dose of gallium Ga-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

#### **DRUG INTERACTIONS**

Androgen deprivation therapy and other therapies targeting the androgen pathway Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga-68 gozetotide PET has not been established.

**Please note that this information summary is not comprehensive.**

**Please see the Full Prescribing Information [here](#).**

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-8638 or emailing [pharmacovigilance@telixpharma.com](mailto:pharmacovigilance@telixpharma.com).

#### Legal Notices

*You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.*

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<sup>1</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

<sup>2</sup> Positron emission tomography.

<sup>3</sup> Prostate-specific membrane antigen.

<sup>4</sup> PSMA-PreRP clinical study. ClinicalTrials.gov ID: [NCT02919111](https://clinicaltrials.gov/ct2/show/study/NCT02919111).

<sup>5</sup> Giesel et al. *Eur J Nucl Med Mol Imaging*. 2015; Alipour et al. *Ther Adv Med Oncol*. 2019; Burgard et al. *Cancers (Basel)*. 2023 and Abghari-Gerst et al. *J Nucl Med*. 2022.

<sup>6</sup> NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.2.2025

<sup>7</sup> NIH Common Cancer Sites — Cancer Stat Facts. Accessed May 2024.

<sup>8</sup> Company analysis based on proprietary and public domain data.

<sup>9</sup> Hospital Outpatient Prospective Payment System (HOPPS) patients eligible for reimbursed PSMA-PET scanning.

<sup>10</sup> Telix has applied for a unique HCPCS code for Gozellix and will also pursue Transitional Pass-through status with Center for Medicare and Medicaid Services (CMS).

- <sup>11</sup> Data on File. Distribution Metrics. Telix Pharmaceuticals. 2023.
- <sup>12</sup> Type II DMF for gallium-68 chloride - DMF# 035947
- <sup>13</sup> Telix ASX disclosure 20 December 2021.
- <sup>14</sup> Telix ASX disclosure 2 November 2021.
- <sup>15</sup> Telix ASX disclosure 14 October 2022.
- <sup>16</sup> Telix ASX disclosure 18 March 2025.
- <sup>17</sup> Telix ASX disclosure 13 February 2025.
- <sup>18</sup> Telix ASX disclosure 21 March 2025.